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SECTION 2 - 510(K) SUMMARY

- **Name and Address of Applicant**

Nihon Kohden America, Inc.
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Attn:
Serrah Namini, Regulatory Affairs Assoc. Dir.

Date: 05/19/2004

- **Name of the device:** WEP-4200A series Central Telemetry System
- **Trade or proprietary name:** WEP-4200A series Central Telemetry System
- **The common or usual name:** Central Telemetry System
- **The classification name:** Physiological Patient Monitor with Arrhytmia Detection and Alarms per 21 CFR Part 870.1025,
- **The legally marketed equivalence:** The predicate device is Nihon Kohden's Central Telemetry system, WEP-8430A, 510K: K945944, dated 11/27/95. All features available with the new WEP-4200 are also available on Nihon Kohden BSM-4104A, 510K: K001693
- **A description of the device:** The system provides for monitoring ECG, ST levels, VPC rate, arrhythmia events, SpO_2, NIBP, temperature, respiration and apnea. The device will be offered with up to 5 multi-connectors and SpO_2. The system is comprised of a receiver (WEP-4200A), and a transmitter (ZS-910P). WEP is a multi-parameter monitor consisting of a color LCD touch-screen to display waveforms and numerics of monitored parameters, multi-parameter receiver unit, visual alarm indicator, external communications port, and a removable battery pack for transmitter. Options include a thermal array recorder and a laser printer interface card.

- **A summary of the technological characteristics of the device compared to the predicate device**:

The telemetry system is intended to monitor, record and display physiological data including ECG, blood oxygen saturation (SpO_2), noninvasive blood pressure (NIBP), body temperature, respiration and apnea. These features are currently available in the legally marketed Nihon Kohden predicate devices, such as WEP-8430 and BSM-4100A series.

The device acquires ECG signals through electrodes placed on the patient. The ECG signals are then amplified, filtered and displayed on a color LCD. Heart rate value is determined from the ECG signal or the pulse waveform and the device may sound an alarm when the heart rate falls outside preset upper and lower limits. These features are currently available in the legally marketed Nihon Kohden predicate devices, such as WEP-8430 and BSM-4100A series.

The device monitors the ECG to detect arrhythmias. User selectable options are provided to control the alarm, storage and recording of arrhythmia events. The device is capable of generating an audible and visual alarm when an arrhythmia event is detected. The device incorporates the same multi-template arrhythmia detection and analysis of the predicate device WEP-8430 and BSM-4100A series.

The device includes a pulse oximeter, which measures the blood oxygen saturation using finger, foot, ear, and multi-site probes and displays a numeric value and a pulse plethysmograph waveform. When the SpO_2 value falls outside preset upper and lower limits, the alarm is activated. The device uses the same control software as the predicate device.

The device includes a noninvasive blood pressure measurement system, which measures and displays the systolic, diastolic, and mean pressures through the use of pressure cuffs placed on the arm or leg. The NIBP measurement interval may be set to manual, continuous or selected time intervals. When NIBP measurements are set to time intervals, the user may also select an additional trigger method called PWTT as offered with the predicate device. An alarm may be generated when the systolic, diastolic or mean pressure values fall outside preset upper and lower limits.

The device measures temperature through the use of the same commercially available temperature thermistors as the predicate device WEP-8430. Temperature thermistors measures temperature through the use of the same commercially available temperature thermistors as the predicate device. The control software for the temperature function is the same in both the new device and the predicate.

The device measures respiration rate through impedance (picked up through the ECG electrodes), through the sensor or through the use of a thermistor respiration pickup transducer. Respiratory waveform is displayed on the monitor and respiration rate is calculated and displayed on the monitor. The device may generate an audible and visual alarm when the measured respiration value falls outside preset upper and lower limits. The software algorithm that determines the respiration rate count is the same in both the new device and the predicate.

A thermal array recorder is available as an option to allow the printing of waveforms and alphanumeric data. Automatic alarm recording, manual recording, and timed recording are available.

All system functions are operable from AC or battery power. A battery charging circuit is incorporated into each device.

- **A summary of the technological differences between the device compared to the predicate devices:**

The new device is an updated version of the WEP-8430A, eight patient telemetry, based on the same technology platform as the BSM-4104A bedside monitor. It uses features and capabilities from the predicate devices.

The transmitting frequency of the new device is in the 608-614 MHz (WMTS) frequency band. The predicate device transmitted in the UHF frequency band. This change was made to meet FCC and FDA recommendations for WMTS.

The new device has more storage memory, which is used to expand the storage of arrhythmia recall files and full disclosure. The basic functions of the arrhythmia recall and full disclosure remain unchanged.

- **Indications for Use:**

The device is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring. The device is intended to present a visual record of the electrical signals produced by the heart and monitor the electrocardiogram to generate visible and/or audible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO_2), noninvasive blood pressure (NIBP), body temperature, respiration rate and apnea. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. The system communicates in the new WMTS band as required by FCC. The device will be available for use by medical personnel on all patient populations within a medical facility, including ICU, CCU, recovery room and general ward.

Non-clinical tests:
The device does not directly contact patients. Accessories that contact patients, such as probes and thermistors, are the same accessories as used with other legally marketed products or are comprised of the same component materials as the predicate accessories. Therefore, good laboratory practice studies were not required per 21 CFR Part 58. The device is in compliance with the FDA Special Controls for arrhythmia detector and alarm system. The device complies with IEC 601-1 sub-clause 56.3(c) implemented by 21 CFR Part 898 Performance Standard for Electrode Lead Wires and Patient Cables. The device is also in compliance with applicable sections of IEC standard as listed in this application.

The device is not sterile.

The device was subjected to electromagnetic, environmental, safety and performance testing procedures. These tests verified the operation of the device. Design validation confirmed the operation of the software functions as well as hardware of the device.

Therefore, Nihon Kohden believes that the device is substantially equivalent to the Nihon Kohden predicate devices as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2004

Nihon Kohden America
c/o Ms. Serrah Namini
RA Assoc. Dir.
90 Icon Street
Foothill Ranch, CA 92610

Re: K040395
Trade Name: WEP-4200A Series Central Telemetry System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: II (two)
Product Code: MHX
Dated: May 25, 2004
Received: May 25, 2004

Dear Ms. Namini:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Neil R.P. Ogden for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): K040395

Device Name: WEP-4200A Series Telemetry system

Indications for Use:

The device is comprised of transmitters and a receiver communicated via WMTS radio frequency. The series of device are intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to produce a visual record of the electrical signals produced by the heart and monitor the electrocardiogram to generate audible and/or visible alarms when an arrhythmia exists. The device is also intended to monitor patients' physiological data including heart rate, pulse rate, blood oxygen saturation (SpO_2) noninvasive blood pressure (NIBP), body temperature respiratory rate and apnea. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. This device receives physiological signals via radio frequency from the transmitters. The device has the capability of communicating with external devices, such as personal computers. Vital sign data can be sent to a central monitor through the network via network card.

The device will be available for use by medical personnel on patients within a medical facility including adults, children and infants.

Neil R P Ogden for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040395

Prescription Use __X____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)